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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): ERWIN et al.
Serial No. 10/684,300
Filed: October 9, 2003
Title: PRODUCTION OF LYSOSOMAL ENZYMES IN PLANTS BY TRANSIENT EXPRESSION
Attorney Docket No. LSBC-0087-DV11

Group Art Unit: 1637
Examiner: Jeffrey N. FREDMAN

COMMISSIONER FOR PATENTS
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450

RESPONSE TO RESTRICTION REQUIRMENT

Sir:

This letter is responsive to the Office Action mailed 02/14/2006 in the above identified application.

AMENDMENT TO THE CLAIMS

Please cancel claims 1, 2, 3, and 5 without prejudice to Applicants' ability to prosecute these claims in another application. Please amend claim 4 as follows.

1. (CANCELLED)A lysosomal enzyme which is enzymatically active and is produced according to a process comprising: recovering the lysosomal enzyme from (i) a plant cell or (ii) a cell, tissue or organ of a plant which plant cell or plant is transfected with a recombinant plant viral expression construct comprising a nucleotide sequence encoding the lysosomal enzyme and a promoter that regulates expression of the nucleotide sequence so that the lysosomal enzyme is expressed by the plant cell or plant.

2. (CANCELLED) The lysosomal enzyme of claim 2, in which the plant is a tobacco plant.

3. (CANCELLED)The lysosomal enzyme of claim 2, in which the lysosomal enzyme is an esterase, .alpha.-N-acetylgalactosaminidase, acid lipase, .alpha.-galactosidase, .alpha.-L-iduronidase, iduronate sulfatase, .alpha.-mannosidase or sialidase.

4. ~~The~~ A method ~~according to claim 3, in which~~ of making a lysosomal enzyme which is enzymatically active, said lysosomal enzyme is made by the method comprising

recovering the lysosomal enzyme from a plant cell, tissue or organ of a plant which plant cell, tissue or organ of the plant is transfected with a recombinant plant viral expression construct comprising a nucleotide sequence encoding the lysosomal enzyme or its sequence complement so that the lysosomal enzyme is expressed by the plant cell, tissue or organ of the plant;

Wherein the lysosomal enzyme is a hydrolase, an exterase, alpha.-N-acetylgalactosaminidase, acid lipase, .alpha.-galactosidase, .alpha.-L-iduronidase, iduronate sulfatase, .alpha.-mannosidase or sialidase or
~~comprises:~~ an enzymatically-active fragment of a hydrolase, an esterase, .alpha.-N-acetylgalactosaminidise, acid lipase, .alpha.-galactosidase, alpha.-L-iduronidase, iduronate sulfatase, .alpha.-mannosidase or sialidase, said enzymatically-active fragment having one or more naturally-occurring amino acid additions, deletions or substitutions.

5. (CANCELLED) The lysosomal enzyme of claim 2 that is a hydrolase.

APPLICANTS' TRAVERSE OF RESTRICTION REQUIREMENT

Applicants elect Group I with traverse. Also, because hydrolase in claim 5 was not made part of the restriction requirement, it is assumed that claim 5 will be examined in its entirety and not just for esterase enzymes.

Applicants respectfully disagree with the restriction and the bases for restriction for the following reasons. The base flaw in the Examiner's argument is that a category called Esterase is lumped in with a small list of specific enzymes. You cannot distinguish a specific enzyme from the class of enzymes called esterases using structure, function and specificity as criteria. If the Examiner abandons Esterases as a member of the class, then where does that leave esterases and hydrolases in the restriction scheme? Further, the Examiner states a conclusion without analysis..

The analysis must begin with MPEP 808.01

> **[808.01 **>Reasons for Holding of Independence or Distinctness< [R-3]**
>
> **>The particular reasons relied on by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate. The reasons upon which the conclusion is based should be given.
>
> For example, relative to a combination and a subcombination thereof, the examiner should point out the reasons why he or she considers the subcombination to have utility by itself or in other combinations, and why he or she considers that the combination as claimed does not require the particulars of the subcombination as claimed.

> Each relationship of claimed inventions should be similarly treated and the reasons for the conclusions of distinctness or independence set forth. Form paragraphs 8.01, 8.02, and 8.14-8.20.02 may be used as appropriate to explain why the inventions as claimed are independent or distinct. See MPEP § 806.05 - § 806.06 <]

A For the restriction to be proper the Examiner must state

- a) Whether this is a normal restriction or a species restriction
- b) That the enzymes are not disclosed or known to be capable of use together, but
- c) That they also have different modes of operation, different functions, or different effects.

These criteria have not been met.

I This restriction requirement appears to have the elements of a species restriction, but it is not stated.

II The Examiner has failed to state whether the first requirement has been met or not. Without stating whether the specification or the literature discloses whether the enzymes are capable of use together, the Examiner has not made a case for a restriction requirement.

III The Examiner has failed to state whether the second requirement has been met or not. The Examiner has not stated whether the different enzymes have a) different modes of operation, b) different functions, or c) different effects. Failing to analyze the modes, functions and effects is fatal to a proper restriction requirement. Without making a statement as to a) different modes of operation, b) different functions, or c) different effects the Examiner has failed to make a case for a proper restriction requirement.

Instead the Examiner makes an arbitrary substitute test. The Examiner states that the enzymes are different a) in structure, b) in function, c) in substrate specificity, d) in methods of use and e) in methods of purification.

MPEP Requirement	Examiner's Test
a) Different Mode	a) Different Structure
b) Different Function	b) Different Function
c) Different Effect	c) Different Specificity
	d) Different Method of Use
	e) Different Method of Purification

None of the three MPEP criteria are analyzed by the Examiner. Further, none of the five substitute criteria are analyzed.

IV Requirements I, II and III must be met to make a restriction requirement. Neither requirement has been made.

Applicants note that in at least one definition of "esterase" the first three requirements; a) different structure, b) different function, c) different substrate specificity are required to differentiate between members of the group. See the definition of ESTERASE at http://www.wisegeek.com/what-is-esterase.htm where Esterase is defined as [Esterase is a type of enzyme that causes esters to split into an acid and an alcohol. There are several kinds of esterase. Three factors set each type of esterase apart from the others: substrate specificity, biological function, and protein structure.]

These do not equate to the second requirement for a restriction. Further, if this is true, then all of the enzymes in groups II-VIII are members of the esterase group, which defines group I. In the absence of the first two criteria being met, this restriction is improper because all of the groups are equivalent to or fall within group I.

B. The Examiner has failed to include "Hydrolase", the subject of claim 5 within the scope of any of the groups that are the subject of the restriction requirement.

It is proper to search all of the enzymes together because there is no clear distinction between for example; modes, functions or effects. One can say what mode, function or effect each enzyme or enzyme in the class uses, but not whether it is distinct from all of the others.

For the reasons given above, Applicants respectfully request that the Examiner withdraw the restriction requirement and either submit a new requirement or search all of the claims together.

Having completed all of the requirements for a patent, Applicants respectfully request an early notice of Allowance.

I hereby certify that this Correspondence is being deposited with the United States Postal Service with sufficient postage for "EXPRESS MAIL Post Office to Addressee in an envelope addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on 11 August 2006.

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Respectfully submitted,

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